INTERNATIONAL DISTRICT COLDE

SOUTHERN DISTRICT OF NEW YORK	
	x
RENEE MASCUNANA,	:
Plaintiff,	. Case No. 07 civ. 7626
vs.	: ECF Case
JOHNSON & JOHNSON, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C. f/k/a R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE, and ORTHOMCNEIL PHARMACEUTICAL, INC.,	: DEFENDANTS' ANSWER, : AFFIRMATIVE DEFENSES AND JURY DEMAND :
Defendants.	:
	:
	X

Defendants Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil"), Johnson & Johnson ("J&J"), and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. ("J&JPRD"), (collectively referred to herein as "Defendants"), by and through their undersigned counsel, hereby respond to the Complaint (the "Complaint") filed by Plaintiff Renee Mascunana ("Plaintiff") as follows:

THE PARTIES

- 1. Defendants are without sufficient knowledge to form a belief as to the truth of the allegations contained in Paragraph 1 of the Complaint.
 - 2. Defendants admit the allegations contained in Paragraph 2 of the Complaint.

- 3. In response to Paragraph 3 of the Complaint, Defendants state that J&J is a holding company that does not manufacture or sell any products in the State of New York. Defendants therefore deny the allegations contained in Paragraph 3 of the Complaint.
 - Defendants admit the allegations contained in Paragraph 4 of the Complaint. 4.
- 5. In response to Paragraph 5 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the contraceptive product known as ORTHO EVRA®. Defendants otherwise deny the allegations contained in Paragraph 5 of the Complaint.
 - 6. Defendants admit the allegations contained in Paragraph 6 of the Complaint.
 - 7. Defendants deny the allegations contained in Paragraph 7 of the Complaint.
 - Defendants admit the allegations contained in Paragraph 8 of the Complaint. 8.
- In response to Paragraph 9 of the Complaint, Defendants admit that Ortho-McNeil 9. and/or J&JPRD designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the contraceptive product known as ORTHO EVRA®. Defendants otherwise deny the allegations contained in Paragraph 9 of the Complaint.
 - Defendants admit the allegations contained in Paragraph 10 of the Complaint. 10.

FACTUAL ALLEGATIONS

- 11. Defendants admit the allegations contained in Paragraph 11 of the Complaint.
- 12. In response to Paragraph 12 of the Complaint, Defendant Ortho-McNeil admits that on the Ortho-McNeil Pharmaceutical, Inc. web site, it states that: "Ortho-McNeil Pharmaceutical is a pioneer in contraception and a leader in women's health care. Ortho-McNeil

offers the broadest range of prescription birth control options...." Defendants otherwise deny the allegations contained in Paragraph 12 of the Complaint.

- 13. Defendants admit the allegations contained in Paragraph 13 of the Complaint.
- 14. Defendants deny the allegations contained in Paragraph 14 of the Complaint.
- 15. Defendants deny the allegations contained in Paragraph 15 of the Complaint.
- 16. In response to Paragraph 16 of the Complaint, Defendants admit that Ortho-McNeil submitted a New Drug Application for approval by the FDA of ORTHO EVRA® as a prescription drug, denoted as NDA 21-180. Defendants otherwise deny the allegations contained in Paragraph 16 of the Complaint.
- 17. In response to Paragraph 17 of the Complaint, Defendants admit that the NDA provides for the prescription use of ORTHO EVRA® for the prevention of pregnancy.

 Defendants otherwise deny the allegations contained in Paragraph 17 of the Complaint.
 - 18. Defendants deny the allegations contained in Paragraph 18 of the Complaint.
 - 19. Defendants deny the allegations contained in Paragraph 19 of the Complaint.
 - 20. Defendants deny the allegations contained in Paragraph 20 of the Complaint.
 - 21. Defendants deny the allegations contained in Paragraph 21 of the Complaint.
- 22. In response to Paragraph 22 of the Complaint, Defendants admit that clinical trials were conducted, pursuant to an FDA approved NDA, which were reviewed by the FDA prior to FDA approval of ORTHO EVRA® for the prescription drug use by physicians. Defendants otherwise deny the allegations contained in Paragraph 22 of the Complaint.
 - 23. Defendants deny the allegations contained in Paragraph 23 of the Complaint.
 - 24. Defendants deny the allegations contained in Paragraph 24 of the Complaint.

- 25. To the extent that Paragraph 25 of the Complaint refers to a document,

 Defendants state that the document speaks for itself and refer to that document for a fair and
 accurate portrayal of its contents. Defendants otherwise deny the allegations contained in

 Paragraph 25 of the Complaint.
- 26. To the extent that Paragraph 26 of the Complaint refers to a document,

 Defendants state that the document speaks for itself and refer to that document for a fair and accurate portrayal of its contents. Defendants otherwise deny the allegations contained in Paragraph 26 of the Complaint.
- 27. In response to Paragraph 27, Defendants admit that the contraceptive product known as ORTHO EVRA® received approval from the Food and Drug Administration as a prescription drug on or about November 20, 2001. Defendants otherwise deny the allegations contained in Paragraph 27 of the Complaint.
 - 28. Defendants deny the allegations contained in Paragraph 28 of the Complaint.
 - 29. Defendants deny the allegations contained in Paragraph 29 of the Complaint.
- 30. To the extent that Paragraph 30 of the Complaint refers to a package insert,

 Defendants state that the package insert speaks for itself and refer to that document for a fair and
 accurate portrayal of its contents. Defendants otherwise deny the allegations contained in

 Paragraph 30 of the Complaint.
- 31. To the extent that Paragraph 31 of the Complaint refers to a package insert,

 Defendants state that the package insert speaks for itself and refer to that document for a fair and
 accurate portrayal of its contents. Defendants otherwise deny the allegations contained in

 Paragraph 31 of the Complaint.

- 32. To the extent that Paragraph 32 of the Complaint refers to a package insert,

 Defendants state that the package insert speaks for itself and refer to that document for a fair and
 accurate portrayal of its contents. Defendants otherwise deny the allegations contained in

 Paragraph 32 of the Complaint.
- 33. To the extent that Paragraph 33 of the Complaint refers to a package insert,

 Defendants state that the package insert speaks for itself and refer to that document for a fair and
 accurate portrayal of its contents. Defendants otherwise deny the allegations contained in

 Paragraph 33 of the Complaint.
 - 34. Defendants deny the allegations contained in Paragraph 34 of the Complaint.
 - 35. Defendants deny the allegations contained in Paragraph 35 of the Complaint.
- 36. In response to Paragraph 36 of the Complaint, Defendants admit that as with all prescription medicine, adverse event reports are reported to the FDA by a variety of people and entities. Defendants otherwise deny the allegations contained in Paragraph 36 of the Complaint.
- 37. In response to Paragraph 37 of the Complaint, Defendants admit that as with all prescription medicine, adverse event reports are reported to the FDA by a variety of people and entities. Defendants otherwise deny the allegations contained in Paragraph 37 of the Complaint.
- 38. In response to Paragraph 38 of the Complaint, Defendants admit that as with all prescription medicine, adverse event reports are reported to the FDA by a variety of people and entities. Defendants otherwise deny the allegations contained in Paragraph 38 of the Complaint.
- 39. In response to Paragraph 39 of the Complaint, Defendants admit that as with all prescription medicine, adverse event reports are reported to the FDA by a variety of people and entities. Defendants otherwise deny the allegations contained in Paragraph 39 of the Complaint.

- Defendants deny the allegations contained in Paragraph 40 of the Complaint. 40.
- Defendants deny the allegations contained in Paragraph 41 of the Complaint. 41.
- 42. Defendants deny the allegations contained in Paragraph 42 of the Complaint.
- 43. Defendants deny the allegations contained in Paragraph 43 of the Complaint.
- 44. Defendants deny the allegations contained in Paragraph 44 of the Complaint.
- 45. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 45 of the Complaint.
- Defendants are without sufficient knowledge or information to form a belief as to 46. the truth of the allegations contained in Paragraph 46 of the Complaint.
- 47. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 47 of the Complaint.
- Defendants are without sufficient knowledge or information to form a belief as to 48. the truth of the allegations contained in Paragraph 48 of the Complaint.
- 49. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 49 of the Complaint.
- To the extent that Paragraph 50 refers to Plaintiff's state of mind, Defendants are 50. without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 50 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 50 of the Complaint.
 - 51. Defendants deny the allegations contained in Paragraph 51 of the Complaint.

FIRST CAUSE OF ACTION STRICT PRODUCTS LIABILITY **DEFECTIVE DESIGN**

- Defendants incorporate by reference each of their responses to all other 52. paragraphs of the Complaint as though fully set forth herein.
- In response to Paragraph 53 of the Complaint, Defendants admit that Ortho-53. McNeil and/or J&JPRD designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the contraceptive product known as ORTHO EVRA®. Defendants otherwise deny the allegations contained in Paragraph 53 of the Complaint.
 - 54. Defendants deny the allegations contained in Paragraph 54 of the Complaint.
 - 55. Defendants deny the allegations contained in Paragraph 55 of the Complaint.
- In response to Paragraph 56, Defendants state that Ortho-McNeil intends for the 56. contraceptive product known as ORTHO EVRA® to reach consumers without substantial change in the condition in which it was sold. Defendants otherwise are without sufficient knowledge to form a belief as to the truth of the remaining allegations contained in Paragraph 56 of the Complaint.
 - 57. Defendants deny the allegations contained in Paragraph 57 of the Complaint.
 - 58. Defendants deny the allegations contained in Paragraph 58 of the Complaint.
 - 59. Defendants deny the allegations contained in Paragraph 59 of the Complaint.

Defendants admit that Plaintiff demands judgment, but Defendants deny that they are liable in any way or that Plaintiff is entitled to any damages or relief whatsoever.

SECOND CAUSE OF ACTION STRICT PRODUCTS LIABILITY MANUFACTURING DEFECT

- 60. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.
- 61. In response to Paragraph 61 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the contraceptive product known as ORTHO EVRA®.

 Defendants otherwise deny the allegations contained in Paragraph 61 of the Complaint.
- 62. In response to Paragraph 62, Defendants state that Ortho-McNeil intends for the contraceptive product known as ORTHO EVRA® to reach consumers without substantial change in the condition in which it was sold. Defendants otherwise are without sufficient knowledge to form a belief as to the truth of the remaining allegations contained in Paragraph 62 of the Complaint.
 - 63. Defendants deny the allegations contained in Paragraph 63 of the Complaint.
 - 64. Defendants deny the allegations contained in Paragraph 64 of the Complaint.

Defendants admit that Plaintiff demands judgment, but Defendants deny that they are liable in any way or that Plaintiff is entitled to any damages or relief whatsoever.

THIRD CAUSE OF ACTION STRICT PRODUCTS LIABILITY FAILURE TO WARN

- 65. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.
 - 66. Defendants deny the allegations contained in Paragraph 66 of the Complaint.

- 67. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 67 of the Complaint.
- 68. To the extent that Paragraph 68 refers to Plaintiff's state of mind, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 68 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 68 of the Complaint.
- 69. The allegations contained in Paragraph 69 of the Complaint are conclusions of law to which no response is required. To the extent a response is required, Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in Paragraph 69 of the Complaint to the extent they suggest any different or greater duties.
 - 70. Defendants deny the allegations contained in Paragraph 70 of the Complaint.
 - 71. Defendants deny the allegations contained in Paragraph 71 of the Complaint.
- 72. To the extent that Paragraph 72 refers to the states of mind of Plaintiff and others, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 72 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 72 of the Complaint.
- 73. The allegations contained in Paragraph 73 of the Complaint are conclusions of law to which no response is required. To the extent a response is required, Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in Paragraph 73 of the Complaint to the extent they suggest any different or greater duties.

- 74. To the extent that Paragraph 74 refers to Plaintiff's state of mind, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 74 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 74 of the Complaint.
 - 75. Defendants deny the allegations contained in Paragraph 75 of the Complaint.

Defendants admit that Plaintiff demands judgment, but Defendants deny that they are liable in any way or that Plaintiff is entitled to any damages or relief whatsoever.

FOURTH CAUSE OF ACTION PRODUCTS LIABILITY BREACH OF IMPLIED WARRANTY

- Defendants incorporate by reference each of their responses to all other 76. paragraphs of the Complaint as though fully set forth herein.
- 77. In response to Paragraph 77 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the contraceptive product known as ORTHO EVRA®. Defendants otherwise deny the allegations contained in Paragraph 77 of the Complaint.
- 78. In response to Paragraph 78 of the Complaint, Defendants admit that Ortho-McNeil and/or J&JPRD designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the contraceptive product known as ORTHO EVRA®. Defendants otherwise deny the allegations contained in Paragraph 78 of the Complaint.
- 79. To the extent that Paragraph 79 refers to the states of mind of Plaintiff and others, Defendants are without sufficient knowledge or information to form a belief as to the truth of the

Page 11 of 19

allegations in Paragraph 79 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 79 of the Complaint.

- 80. Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 80 of the Complaint.
 - 81. Defendants deny the allegations contained in Paragraph 81 of the Complaint.
 - 82. Defendants deny the allegations contained in Paragraph 82 of the Complaint.
 - 83. Defendants deny the allegations contained in Paragraph 83 of the Complaint.

Defendants admit that Plaintiff demands judgment, but Defendants deny that they are liable in any way or that Plaintiff is entitled to any damages or relief whatsoever.

FIFTH CAUSE OF ACTION PRODUCTS LIABILITY NEGLIGENCE

- 84. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.
- 85. The allegations contained in Paragraph 85 of the Complaint are conclusions of law to which no response is required. To the extent a response is required, Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in Paragraph 85 of the Complaint to the extent they suggest any different or greater duties.
 - 86. Defendants deny the allegations contained in Paragraph 86 of the Complaint.
 - 87. Defendants deny the allegations contained in Paragraph 87 of the Complaint.
 - 88. Defendants deny the allegations contained in Paragraph 88 of the Complaint.
 - 89. Defendants deny the allegations contained in Paragraph 89 of the Complaint.

Defendants admit that Plaintiff demands judgment, but Defendants deny that they are liable in any way or that Plaintiff is entitled to any damages or relief whatsoever.

SIXTH CAUSE OF ACTION BREACH OF EXPRESS WARRANTY

- 90. Defendants incorporate by reference each of their responses to all other paragraphs of the Complaint as though fully set forth herein.
 - 91. Defendants deny the allegations contained in Paragraph 91 of the Complaint.
 - 92. Defendants deny the allegations contained in Paragraph 92 of the Complaint.
 - 93. Defendants deny the allegations contained in Paragraph 93 of the Complaint.
- 94. To the extent that Paragraph 94 refers to the states of mind of others, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 94 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 94 of the Complaint.
- 95. To the extent that Paragraph 95 refers to Plaintiff's state of mind, Defendants are without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 95 of the Complaint. Defendants otherwise deny the remaining allegations contained in Paragraph 95 of the Complaint.
 - Defendants deny the allegations contained in Paragraph 96 of the Complaint. 96.
 - 97. Defendants deny the allegations contained in Paragraph 97 of the Complaint.

Defendants admit that Plaintiff demands judgment, but Defendants deny that they are liable in any way or that Plaintiff is entitled to any damages or relief whatsoever.

AFFIRMATIVE DEFENSES

For further answer to Plaintiff's Complaint, Defendants respectfully aver:

FIRST AFFIRMATIVE DEFENSE

Plaintiff's Complaint, or certain counts, fails to state a claim against Defendants upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

If the injuries and damages alleged by Plaintiff in the Complaint were actually sustained, such damages and injuries resulted from a preexisting and/or unrelated medical condition and/or idiosyncratic reaction and not from any act or omission on behalf of Defendants or a defect in ORTHO EVRA®.

THIRD AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiff in the Complaint may have been caused, in whole or in part, by the acts or omissions of others for whose conduct Defendants are not responsible.

FOURTH AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiff in the Complaint were caused, brought about or contributed to by her own comparative fault, and any recovery by Plaintiff must therefore be reduced proportionately or altogether barred.

FIFTH AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiff in the Complaint were the result of an independent, intervening, and/or superseding cause. Any alleged action or alleged omission on the part of Defendants was not the proximate cause of such damages and injuries.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred or reduced by the doctrine of avoidable consequences.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff has failed to obtain jurisdiction over Defendants.

EIGHTH AFFIRMATIVE DEFENSE

The United States Food and Drug Administration ("FDA") approved the labeling for ORTHO EVRA®, and the marketing and/or distribution of ORTHO EVRA® conformed with FDA requirements and all other applicable statutes at all times pertinent to the Complaint.

NINTH AFFIRMATIVE DEFENSE

Because the FDA approved ORTHO EVRA®, Plaintiff's claims that Defendants are strictly liable are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and/or the Restatement (Third) of Torts: Products Liability §§ 2, 4 and 6 and comments thereto.

TENTH AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiff in the Complaint are or may be due to her assumption of the risk of use of ORTHO EVRA®, if any, thereby barring Plaintiff from recovery.

ELEVENTH AFFIRMATIVE DEFENSE

Adequate and complete warnings and instructions were provided with ORTHO EVRA®. ORTHO EVRA® was neither defective nor unreasonably dangerous when used according to label instructions.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of express or implied warranty are barred by Plaintiff's failure to give notice.

THIRTEENTH AFFIRMATIVE DEFENSE

Any express or implied warranties alleged to have been made by Defendants were disclaimed.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are barred by the absence of privity of contract between Plaintiff and Defendants.

FIFTEENTH AFFIRMATIVE DEFENSE

Defendants are entitled to the benefit of all defenses and presumptions which may arise because the design, manufacture, inspection, packaging, issuing of warnings and instructions or labeling of ORTHO EVRA® were in conformity with the generally recognized, reasonably available and reliable state of the art and prevailing standards in the industry at the time the product was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by the Learned Intermediary Doctrine, or the Informed Intermediary Doctrine and/or the principle of Restatement (Second) of Torts § 388.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that the FDA is charged under the law with regulating prescription drugs, including ORTHO EVRA®, and is specifically charged with determining the content of warnings and labeling for prescription drugs.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims, in whole or in part, are preempted expressly and impliedly by the Supremacy Clause of the Constitution of the United States of America and by applicable federal statutes and regulations thereunder.

NINETEENTH AFFIRMATIVE DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341 (2001).

TWENTIETH AFFIRMATIVE DEFENSE

If Defendants are found liable to Plaintiff for any non-economic loss, as defined in Article 16 of the New York Civil Practice Law and Rules, and such liability equals 50% or less of the total liability of all persons liable, and the aggregate liability of such other persons equals or exceeds 50% of the total liability, Defendants' liability, if any, to Plaintiff for a non-economic loss shall not exceed Defendants' equitable share determined in accordance with the relative culpability of each person causing or contributing to the total liability for such non-economic loss.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The awarding of punitive damages and Plaintiff's claims for punitive damages are unconstitutional under the constitutions of the United States and the State of New York. The awarding of punitive damages would be unconstitutional because punitive damages are a punishment, a quasi-criminal sanction for which Defendants have not been afforded the specific procedural safeguards prescribed in the New York Constitution as well as the Fifth and Sixth

Amendments to the United States Constitution, and would violate constitutional proscriptions against excessive fines.

TWENTY-SECOND AFFIRMATIVE DEFENSE

With respect to Plaintiff's demand for punitive damages, Defendants specifically incorporate by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of BMW of North

America v. Gore, 517 U.S. 559 (1996); Cooper Industries, Inc. v. Leatherman Tool Group, Inc.,
532 U.S. 424 (2001); State Farm Mutual Auto Ins. Co. v. Campbell, 538 U.S. 408 (2003); and

Philip Morris USA v. Williams, 549 U.S. ____, 127 S. Ct. 1057 (2007), together with all such standards applicable under New York law.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the First Amendment of the Constitution of the United States and Article I, Section 8 of the Constitution of the State of New York.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Any recovery by Plaintiff must be reduced or offset by amounts Plaintiff has received or will receive from others for the same injuries and damages alleged by Plaintiff in the Complaint pursuant to Section 15-108 of the General Obligation Law.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's causes of action are barred in whole or in part by the applicable statutes of limitations or repose, or by operation of laches.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's causes of action are barred in whole or in part by the doctrines of waiver and equitable estoppel.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Any damages allegedly recoverable by Plaintiff should be reduced in accordance with Rule 4545 of the New York Civil Practice Law and Rules.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because Defendants did not owe any legal duty to Plaintiff or, if Defendants did owe such a legal duty, Defendants did not breach that duty.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by her abuse and/or misuse of the ORTHO EVRA® product.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims must be dismissed because venue in the United States District Court for the Southern District of New York is not proper as the Southern District of New York is an inconvenient forum for the parties.

THIRTY-FIRST AFFIRMATIVE DEFENSE

To the extent not incorporated above, Defendants raise all affirmative defenses available under the law of the forum in which the alleged cause of action arose.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Defendants specifically deny each and every allegation contained in the Complaint by which liability is sought to be imposed upon it, and give notice that they intend to rely upon such

other defenses as may become available or appear during discovery in this case and hereby reserve the right to amend this Answer to assert any such defenses.

WHEREFORE, having fully answered, Defendants request that Plaintiff's Complaint against it be dismissed at Plaintiff's cost and that this Court grant any further relief which it deems just and equitable.

JURY DEMAND

Defendants hereby demand a trial by jury of all the facts and issues so triable pursuant to 38(b) of the Federal Rules of Civil Procedure.

Respectfully submitted,

Dated: August 29, 2007

/s/ Patrick G. Broderick

Robert W. Sparks (RS 4250) Debra D. O'Gorman (DO 1643) Patrick G. Broderick (PB 7282) James S. Buino (JB 1980) **DECHERT LLP** 30 Rockefeller Plaza, New York, NY 10112-2200 (212) 698-3500

Attorneys for Defendants